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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,885	01/25/2006	Juan Lopez De Silanes	23990080000JAGLAV	8053

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EXAMINER	
SKELDING, ZACHARY S	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
04/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,885	LOPEZ DE SILANES ET AL.	
	Examiner	Art Unit	
	ZACHARY SKELDING	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *20-61* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment to the claims filed January 25, 2006 is acknowledged.

   Claims 1-19 have been canceled.

   Claims 20-61 have been added.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

3. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

4. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

   Group I, claim(s) 36, drawn to a method for treating cytokine-mediated immune reactions in a patient in need thereof comprising, topically administering to a human in need of such treatment an effective amount of anti-TNFα F(ab')2 antibody fragments.

   Group II, claim(s) 37, drawn to a method for treating cytokine-mediated immune reactions in a patient in need thereof comprising, topically administering to a human in need of such treatment an effective amount of anti-TNFβ F(ab')2 antibody fragments.

   Group III, claim(s) 40, drawn to a method for treating cytokine-mediated immune reactions in a patient in need thereof comprising, topically administering to a human in need of such treatment an effective amount of anti-IL-1α F(ab')2 antibody fragments.

   Group IV, claim(s) 41, drawn to a method for treating cytokine-mediated immune reactions in a patient in need thereof comprising, topically administering to a human in need of such treatment an effective amount of anti-IL-1β F(ab')2 antibody fragments.

   Group V, claim(s) 42, drawn to a method for treating cytokine-mediated immune reactions in a patient in need thereof comprising, topically administering to a human in need of such treatment an effective amount of anti-IL-2 F(ab')2 antibody fragments.

   Group VI, claim(s) 43, drawn to a method for treating cytokine-mediated immune reactions in a patient in need thereof comprising, topically administering to a human

in need of such treatment an effective amount of anti-IL-6 F(ab')2 antibody fragments.

Group VII, claim(s) 44, drawn to a method for treating cytokine-mediated immune reactions in a patient in need thereof comprising, topically administering to a human in need of such treatment an effective amount of anti-IL-12 F(ab')2 antibody fragments.

Group VIII, claim(s) 45, drawn to a method for treating cytokine-mediated immune reactions in a patient in need thereof comprising, topically administering to a human in need of such treatment an effective amount of anti-IFN-γ F(ab')2 antibody fragments.

Group IX, claim(s) 48, drawn to the use of anti-TNFα F(ab')2 antibody fragments for the manufacture of a medicament for the treatment of cytokine-mediated immune reaction in a patient in need thereof, wherein said medicament is suitable for topical administration.

Group X, claim(s) 49, drawn to the use of anti-TNFβ F(ab')2 antibody fragments for the manufacture of a medicament for the treatment of cytokine-mediated immune reaction in a patient in need thereof, wherein said medicament is suitable for topical administration.

5. Claims 20-35 and 46 link(s) the inventions of Group I-VIII.
The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 20-35 and 46.

Claims 20-35, 38 and 39 link(s) the inventions of Group III-VII.
The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 20-35, 38 and 39.

Claims 47 and 50-61 link(s) the inventions of Groups IX and X.
The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 47 and 50-61.

Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

6. The inventions listed as Groups I-X above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the inventions of Groups I-X do not share a special technical feature that defines a contribution over the prior art of Feldman et al., U.S. Patent No. 6270766.

   In particular, Feldman teaches a method of treating rheumatoid arthritis by topically administering anti-TNFα F(ab')2 antibody fragments (see Feldman column 12, 1st paragraph, column 18, 2nd paragraph and claim 1).

   Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

7. This application also contains claims directed to more than one species of the generic invention.

   These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under **PCT Rule 13.1**.

   Applicant is required, in reply to this action, to elect a single species, as applicable, which the claims shall be restricted if no generic claim is finally held to be allowable, chosen from among the particular species recited, for example, in claim 22, “psoriasis vulgaris” or claim 25, "rheumatoid arthritis,” or claim 28 “keratitis” or claim 30 “septic shock” etc.

   Applicant should note that a particular species of disease, as recited, must be elected, not a genus that encompasses multiple claimed species, for example, electing the claimed genus “chronic inflammatory disease” will not be considered responsive; however electing the particular claimed species “rheumatoid arthritis" would be considered responsive.

   The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

   Applicant is required, in reply to this action, to elect a single species, as applicable, which the claims shall be restricted if no generic claim is finally held to be allowable.

The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by **37 CFR 1.141**. If claims are added after the election, applicant must indicate which are readable upon the elected species. **MPEP § 809.02(a)**.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZACHARY SKELDING whose telephone number is (571)272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.
Patent Examiner
March 29, 2008

/Michail A Belyavskyi/
Primary Examiner, Art Unit 1644